

Appl. No.: 09/913,377  
Group Art Unit: 1616  
Applicants' Reply to the Office Action dated May 4, 2004

**REMARKS**

Claims 9-37 are currently pending in the instant application.

In the Office Action, the Examiner reiterates that claims 9-34 are allowed.

Additionally, in the Office Action, the Examiner has withdrawn her rejection of claims 35-37 under 35 U.S.C. §102(e), as being anticipated by U.S. Pat. No. 6,107,456 of Huibers, *et al.*

However, in the Office, the Examiner now rejects claims 35 and 36 under 35 U.S.C. §102(b), as being anticipated by U.S. Pat. No. 4,963,346 of Amer, (hereinafter referred to as "Amer"). Specifically, the Examiner contends that Amer discloses a composition comprising at least about 80%, and most preferably at least about 99% phytosterols. The Examiner argues that the composition disclosed by Amer "is encompassed by the instant claims." (See, the Office Action, ¶ 4). On this basis, the Examiner argues that the claimed invention is anticipated.

Applicants respectfully traverse the Examiner's rejection, along with the contentions and arguments in support thereof for the following reasons.

The rejected embodiments of Applicants' claimed invention are directed to products prepared by the processes according to claims 9 and 34, respectively, wherein a major portion of the product comprises a phytosterol, and wherein the processes comprise, in general:

(a) providing a liquid phytosterol starting material obtained by transesterification of a distillation residue with an alkanol;

(b) dissolving the liquid phytosterol starting material in a hydrocarbon solvent; and

(c) crystallizing a phytosterol product, *wherein the phytosterol product is substantially citrostadienol-free.*

In order for a rejection under 35 U.S.C. §102(b) to be proper, each and every element of the claimed invention must be taught, either expressly or inherently, in a single prior art reference. (See, e.g., M.P.E.P. §2131).

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Amer fails to teach, either expressly or inherently, a composition which comprises a major portion of a phytosterol *and which is substantially citrostadienol-free*. Accordingly, Amer fails to anticipate the claimed invention. Amer is directed to a composition which comprises at least about 80% phytosterols, and most preferably, at least about 99% phytosterols. *Citrostadienol is a phytosterol*. Nowhere in Amer does the reference indicate that the compositions are substantially free of citrostadienol. In fact, to the contrary, Amer specifically describes a *purified* product according to the invention which contains 84.48% phytosterols, of which up to about 3.1% may comprise citrostadienol. (See, Amer, col. 8, lines 15-24). Amer describes a composition containing 84.48% phytosterols, 21.3% of which is campesterol, 19.2% of which is stigmasterol, and 40.9% of which is  $\beta$ -sitosterol. Amer indicates that the remainder of the phytosterol content is cycloartenol, *citrostadienol* and other phytosterols. Thus, at least some portion of the remaining 3.1% ( $84.5 - 21.3 - 19.2 - 40.9 = 3.1\%$ ) comprises citrostadienol, and certainly a substantial portion of the 3.1% as it warranted specific mention among the "other phytosterols". (See, *id.*).

Amer specifically discloses the presence of citrostadienol in the disclosed compositions, and in an amount significant enough to warrant specific mention among "other phytosterols". There is absolutely nothing in the disclosure of Amer which indicates that citrostadienol ought to be precluded from the composition in favor of all other phytosterols.

Accordingly, Applicants respectfully submit that Amer can not be held to anticipate the claimed invention which is directed to products that are substantially citrostadienol-free. Thus, reconsideration and withdrawal of the rejection of claims 35 and 36 under 35 U.S.C. §102(b), based on Amer, are respectfully requested.

In the Office Action, the Examiner also rejects claims 35-37 under 35 U.S.C. §103(a), as being unpatentable over Amer. Specifically, the Examiner contends that Amer discloses compositions containing large amounts of phytosterols, as mentioned in support of the Examiner's rejection under §102(b). The Examiner acknowledges that Amer fails to teach a phytosterol composition having 0.5 % by weight or less of citrostadienol. However, the Examiner argues that,

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" . . . based on the teachings of Amer and the knowledge in the pharmaceutical art that increase purification reduces adverse effects of pharmaceuticals, the skilled artisan would be motivated to obtain a composition having 99% or higher phytosterol with the reasonable expectation that the composition would be useful as taught by the prior art." (See, the Office Action, ¶ 6 (*emphasis added*)).

On this basis, the Examiner argues that the claimed invention is obvious. Applicants respectfully traverse the Examiner's rejection, along with the contentions and arguments in support thereof for the following reasons.

In order to establish *prima facie* obviousness based upon a single reference, and thus shift the burden of proving non-obviousness onto Applicants, the Examiner must establish all of the following three criteria based on the single reference: (1) the reference must contain a teaching or suggestion which would motivate one of ordinary skill in the art to modify the reference as suggested by the Examiner (it is not sufficient to say that the reference can be combined without a teaching in the cited reference to suggest the desirability of such a modification); (2) there must be a reasonable expectation of success; and (3) the reference must teach or suggest each and every element of Applicant's claimed invention. (M.P.E.P. §2143).

As discussed above, the rejected embodiments of Applicants' claimed invention are directed to products prepared by the processes according to claims 9 and 34, respectively, wherein a major portion of the product comprises a phytosterol, and *wherein the phytosterol product is substantially citrostadienol-free*. Additionally, Applicants' claimed invention, as embodied in claim 37, is directed to a composition comprising one or more natural phytosterol compounds, wherein the composition has a citrostadienol content of 0.5% by weight or less.

To begin with, there is absolutely nothing in the disclosure of Amer which teaches or suggests that the content of citrostadienol ought to be minimized. Citrostadienol IS a phytosterol. Increasing the *total content* of phytosterols in general, without any teaching or suggestion to remove citrostadienol in particular over all other phytosterols, would necessarily increase the content of citrostadienol as well. Thus, the Examiner's argument with respect to

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obtaining a composition having 99% or higher phytosterol is to no avail in obviating a the claimed invention, as the phytosterols are inclusive of citrostadienol.

As mentioned, there is no explicit teaching to reduce the content of citrostadienol. Moreover, there is no indication that the presence of citrostadienol is detrimental, and thus, there can be no suggestion that its content ought to be reduced in comparison to any other phytosterol. Accordingly, it is also submitted that the reference fails to suggest a reduction in the content of this particular phytosterol.

Nothing contained in the Amer reference would motivate one of ordinary skill in the art to modify the reference to arrive at Applicants' claimed invention of a composition comprising a major portion of phytosterols and also being substantially citrostadienol-free. Amer specifically notes a substantial citrostadienol content and makes no mention whatsoever that this presence of citrostadienol is negative or to be avoided. Therefore, one of ordinary skill in the art would find no motivation in the teachings of Amer to specifically remove it as opposed to all other phytosterols.

Lastly, given the lack of any teaching or suggestion to reduce the content of citrostadienol, and the lack of any teaching which would motivate such a modification, it cannot reasonably be said that one of ordinary skill in the art would expect success in such an alteration of the Amer reference.

Accordingly, Applicants respectfully submit that the Examiner has failed to establish a *prima facie* case of obviousness based upon the Amer reference. Reconsideration and withdrawal of the obviousness rejection based upon Amer are respectfully requested.

In view of the comments set forth above, Applicants submit that all pending claims patentably distinguish over the prior art of record and known to Applicants, either alone or in combination. Accordingly, reconsideration, withdrawal of the rejections and a Notice of Allowance for all pending claims are respectfully requested.

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Respectfully submitted,

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